CHAPTER 19 – HEALTH: EPIDEMIOLOGY

SUBCHAPTER 19A – COMMUNICABLE DISEASE CONTROL

SECTION .0100 - REPORTING OF COMMUNICABLE DISEASES

15A NCAC 19A .0101 REPORTABLE DISEASES AND CONDITIONS

(a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

(1) acquired immune deficiency syndrome (AIDS) - 7 days;
(2) anthrax - 24 hours;
(3) botulism - 24 hours;
(4) brucellosis - 7 days;
(5) campylobacter infection - 24 hours;
(6) chancroid - 24 hours;
(7) chlamydial infection (laboratory confirmed) - 7 days;
(8) cholera - 24 hours;
(9) Creutzfeldt-Jakob disease – 7 days;
(10) cryptosporidiosis - 24 hours;
(11) cyclosporiasis - 24 hours;
(12) dengue - 7 days;
(13) diphtheria - 24 hours;
(14) Escherichia coli, shiga toxin-producing - 24 hours;
(15) ehrlichiosis - 7 days;
(16) encephalitis, arboviral - 7 days;
(17) enterococci, vancomycin-resistant, from normally sterile site - 7 days;
(18) foodborne disease, including but not limited to Clostridium perfringens, staphylococcal, and Bacillus cereus - 24 hours;
(19) gonorrhea - 24 hours;
(20) granuloma inguinale - 24 hours;
(21) Haemophilus influenzae, invasive disease - 24 hours;
(22) Hantavirus infection – 7 days;
(23) Hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura - 24 hours;
(24) Hemorrhagic fever virus infection – 24 hours;
(25) hepatitis A - 24 hours;
(26) hepatitis B - 24 hours;
(27) hepatitis B carriage - 7 days;
(28) hepatitis C, acute - 7 days;
(29) human immunodeficiency virus (HIV) infection confirmed - 7 days;
(30) legionellosis - 7 days;
(31) leptospirosis - 7 days;
(32) listeriosis – 24 hours;
(33) Lyme disease - 7 days;
(34) lymphogranuloma venereum - 7 days;
(35) malaria - 7 days;
(36) measles (rubeola) - 24 hours;
(37) meningitis, pneumococcal - 7 days;
(38) meningococcal disease - 24 hours;
(39) mumps - 7 days;
(40) nongonococcal urethritis - 7 days;
(41) plague - 24 hours;
(42) paralytic poliomyelitis - 24 hours;
(43) psittacosis - 7 days;
(44) Q fever - 7 days;

(45) rabies, human - 24 hours;
(46) Rocky Mountain spotted fever - 7 days;
(47) rubella - 24 hours;
(48) rubella congenital syndrome - 7 days;
(49) salmonellosis - 24 hours;
(50) shigellosis - 24 hours;
(51) smallpox – 24 hours;
(52) streptococcal infection, Group A, invasive disease - 7 days;
(53) syphilis - 24 hours;
(54) tetanus - 7 days;
(55) toxic shock syndrome - 7 days;
(56) toxoplasmosis, congenital - 7 days;
(57) trichinosis - 7 days;
(58) tuberculosis - 24 hours;
(59) tularemia - 24 hours;
(60) typhoid - 24 hours;
(61) typhoid carriage (Salmonella typhi) - 7 days;
(62) typhus, epidemic (louse-borne) - 7 days;
(63) vaccinia – 24 hours;
(64) vibrio infection (other than cholera) - 24 hours;
(65) whooping cough - 24 hours;
(66) yellow fever - 7 days.

(b) For purposes of reporting; confirmed human immunodeficiency virus (HIV) infection is defined as a positive virus culture; repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test; positive polymerase chain reaction (PCR) test; or other confirmed testing method approved by the Director of the State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association of Public Health Laboratories.

(c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified in G.S. 130A-139, laboratories shall report:

(1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
  (A) Any hantavirus or hemorrhagic fever virus.
  (B) Arthropod-borne virus (any type).
  (C) Bacillus anthracis, the cause of anthrax.
  (D) Bordetella pertussis, the cause of whooping cough (pertussis).
  (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
  (F) Brucella spp., the causes of brucellosis.
  (G) Campylobacter spp., the causes of campylobacteriosis.
  (H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
  (I) Clostridium botulinum, a cause of botulism.
  (J) Clostridium tetani, the cause of tetanus.
  (K) Corynebacterium diphtheriae, the cause of diphtheria.
  (L) Coxiella burnetii, the cause of Q fever.
  (M) Cryptosporidium parvum, the cause of human cryptosporidiosis.
  (N) Cyclospora cayetanesis, the cause of cyclosporiasis.
  (O) Ehrlichia spp., the causes of ehrlichiosis.
  (P) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
  (Q) Francisella tularensis, the cause of tularemia.
  (R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
  (S) Human Immunodeficiency Virus, the cause of AIDS.

(T) Legionella spp., the causes of legionellosis.
(U) Leptospira spp., the causes of leptospirosis.
(V) Listeria monocytogenes, the cause of listeriosis.
(W) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.
(X) Poliovirus (any), the cause of poliomyelitis.
(Y) Rabies virus.
(Z) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
(AA) Rubella virus.
(BB) Salmonella spp., the causes of salmonellosis.
(CC) Shigella spp., the causes of shigellosis.
(DD) Smallpox virus, the cause of smallpox.
(EE) Trichinella spiralis, the cause of trichinosis.
(FF) Vaccinia virus.
(GG) Vibrio spp., the causes of cholera and other vibrioses.
(HH) Yellow fever virus.
(II) Yersinia pestis, the cause of plague.

(2) Isolation or other specific identification of the following organisms from normally sterile human body sites:
(A) Group A Streptococcus pyogenes (group A streptococci).
(B) Haemophilus influenzae, serotype b.
(C) Neisseria meningitidis, the cause of meningococcal disease.
(D) Vancomycin-resistant Enterococcus spp.

(3) Positive serologic test results, as specified, for the following infections:
(A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
(i) Any arthropod-borne viruses associated with meningitis or encephalitis in a human.
(ii) Any hantavirus or hemorrhagic fever virus.
(iii) Chlamydia psittaci, the cause of psittacosis.
(iv) Coxiella burnetii, the cause of Q fever.
(v) Dengue virus.
(vi) Ehrlichia spp., the causes of ehrlichiosis.
(vii) Measles (rubeola) virus.
(viii) Mumps virus.
(ix) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
(x) Rubella virus.
(xi) Yellow fever virus.
(B) The presence of IgM serum antibodies to:
(i) Chlamydia psittaci
(ii) Hepatitis A virus.
(iii) Hepatitis B virus core antigen.
(iv) Rubella virus.
(v) Rubeola (measles) virus.
(vi) Yellow fever virus.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. October 1, 1994; February 1, 1990;
Temporary Amendment Eff. July 1, 1997;
Amended Eff. August 1, 1998;
Temporary Amendment Eff. February 13, 2003; October 1, 2002; February 18, 2002; June 1, 2001.

15A NCAC 19A .0102 METHOD OF REPORTING

(a) When a report of a disease or condition is required to be made pursuant to G.S. 130A-135 through 139 and 15A NCAC 19A .0101, the report shall be made to the local health director as follows:

(1) For diseases and conditions required to be reported within 24 hours, the initial report shall be made by telephone, and the report required by Subparagraph (2) of this Paragraph shall be made within seven days.

(2) In addition to the requirements of Subparagraph (1) of this Paragraph, the report shall be made on the communicable disease report card or in an electronic format provided by the Division of Epidemiology and shall include the name and address of the patient, the name and address of any minor's parent or guardian, and all other pertinent epidemiologic information.

(3) Until September 1, 1994, reports of cases of confirmed HIV infection identified by anonymous tests that are conducted at HIV testing sites designated by the State Health Director pursuant to 15A NCAC 19A .0202(10) shall be made on forms provided by the Department for that purpose. No communicable disease report card shall be required. Effective September 1, 1994, anonymous testing shall be discontinued and all cases of confirmed HIV infection shall be reported in accordance with 15A NCAC 19A .0102(a)(1) and (2).

(4) In addition to the requirements of Subparagraphs (1) and (2) of this Paragraph, forms or electronic formats provided by the Division of Epidemiology for collection of information necessary for disease control and documentation of clinical and epidemiologic information about the cases shall be completed and submitted for the reportable diseases and conditions identified in 15A NCAC 19A .0101(1), (4), (13), (20), (21), (22), (23), (24), (25), (26), (27), (28), (29), (31), (32), (33), (34), (35), (38), (39), (42), (43), (44), (49), (50), (52), (53), (54), (55), (56), and (59).

(5) Communicable disease report cards, surveillance forms, and electronic formats are available from the Surveillance Unit, N.C. Division of Epidemiology, P.O. Box 29601, Raleigh, NC 27626-0601, (919) 733-3419, and from local health departments.

(b) Notwithstanding the time frames established in 15A NCAC 19A .0101 a restaurant or other food or drink establishment shall report all outbreaks or suspected outbreaks of foodborne illness in its customers or employees and all suspected cases of foodborne disease or foodborne condition in food-handlers at the establishment by telephone to the local health department within 24 hours in accordance with Subparagraph (a)(1) of this Rule. However, the establishment is not required to submit a report card or surveillance form pursuant to Subparagraphs (a)(2) and (a)(4) of this Rule.

(c) For the purposes of reporting by restaurants and other food or drink establishments pursuant to G.S. 130A-138, the diseases and conditions to be reported shall be those listed in 15A NCAC 19A .0101(3), (5), (8), (9), (12), (16), (21), (44), (45), (51), (54), (55), and (57).

(d) Laboratories required to report test results pursuant to G.S. 130A-139 and 15A NCAC 19A .0101(c) shall report as follows:

(1) The results of the specified tests for syphilis and gonorrhea shall be reported to the local health department by the first and fifteenth of each month. Reports of the results of the specified tests for gonorrhea and syphilis shall include the specimen collection date, the patient's age, race, and sex, and the submitting physician's name, address, and telephone numbers.

(2) Positive darkfield examinations for syphilis and STS titers of 1:16 and above shall be reported within 24 hours by telephone to the HIV/STD Control Branch at (919) 733-7301, or the HIV/STD Control Branch Regional Office where the laboratory is located.

(3) With the exception of positive laboratory tests for human immunodeficiency virus, positive laboratory tests as defined in G.S. 130A-139(1) and 15A NCAC 19A .0101(c) shall be reported to the General Communicable Disease Control Section within the time periods specified for each reportable disease or condition in 15A NCAC 19A .0101(a). Confirmed positive laboratory tests for human immunodeficiency virus as defined in 15A NCAC 19A .0101(b) shall be reported to the HIV/STD Control Section within seven days of obtaining reportable test results. Reports shall include as much of the following information as the laboratory possesses: the specific name of the test performed; the source of the specimen;

the collection date(s); the patient=s name, age, race, and sex; and the submitting physician=s name, address, and telephone number.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-138; 130A-139; 130A-141;*
Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
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Amended Eff. October 1, 1994; February 3, 1992; December 1, 1991; May 1, 1991;

Filed as a Temporary Amendment Eff. December 16, 1994, for a period of 180 days or until the
permanent rule becomes effective, whichever is sooner;
Temporary Amendment Expired June 16, 1995;
Amended Eff. August 1, 1998.

15A NCAC 19A .0103 DUTIES LOCAL HEALTH DIRECTOR: REPORT COMMUNICABLE DISEASES

(a) Upon receipt of a report of a communicable disease or condition pursuant to 15A NCAC 19A .0101, the local health director shall:

(1) immediately investigate the circumstances surrounding the occurrence of the disease or condition to determine the authenticity of the report and the identity of all persons for whom control measures are required. This investigation shall include the collection and submission for laboratory examination of specimens necessary to assist in the diagnosis and indicate the duration of control measures;

(2) determine what control measures have been given and ensure that proper control measures as provided in 15A NCAC 19A .0201 have been given and are being complied with;

(3) forward the report as follows:

(A) The local health director shall forward all authenticated reports made pursuant to G.S. 130A-135 to 137 of syphilis, chancroid, granuloma inguinale, and lymphogranuloma venereum within seven days to the regional office of the HIV/STD Control Branch. In addition, the local health director shall telephone reports of all cases of primary, secondary, and early latent (under one year's duration) syphilis to the regional office of the HIV/STD Control Branch within 24 hours of diagnosis at the health department or report by a physician.

(B) The local health director shall telephone all laboratory reports of reactive syphilis serologies to the regional office of the HIV/STD Control Branch within 24 hours of receipt if the person tested is pregnant. This shall also be done for all other persons tested unless the dilution is less than 1:8 and the person is known to be over 25 years of age or has been previously treated. In addition, the written reports shall be sent to the regional office of the HIV/STD Control Branch within seven days.

(C) Except as provided in (a)(3)(A) and (B) of this Rule, a local health director who receives a report pursuant to 15A NCAC 19A .0102 regarding a person residing in that jurisdiction shall forward the authenticated report to the Division of Epidemiology within seven days.

(D) Except as provided in (a)(3)(A) and (B) of this Rule, a local health director who receives a report pursuant to 15A NCAC 19A .0102 regarding a person who resides in another jurisdiction in North Carolina shall forward the report to the local health director of that jurisdiction within 24 hours. A duplicate report card marked "copy" shall be forwarded to the Division of Epidemiology within seven days.

(E) A local health director who receives a report pursuant to 15A NCAC 19A .0102 regarding a person who resided outside of North Carolina at the time of onset of the illness shall forward the report to the Division of Epidemiology within 24 hours.

(b) Whenever a cluster of cases of a reportable disease or condition occurs, the local health director shall investigate the cluster to determine if an outbreak exists. If an outbreak exists, the local health director shall

submit to the Division of Epidemiology within 30 days a written report of the investigation, its findings, and the actions taken to control the outbreak and prevent a recurrence.
(c) Whenever a cluster of cases of a disease or condition occurs which is not required to be reported by 15A NCAC 19A .0101 but which represents a significant threat to the public health, the local health director shall investigate the cluster to determine if an outbreak exists. If an outbreak exists, the local health director shall give appropriate control measures consistent with 15A NCAC 19A .0200, and inform the Division of Epidemiology of the circumstances of the outbreak within seven days.

History Note: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-141; 130A-144;
Eff. March 1, 1988;
Amended Eff. December 1, 1991; September 1, 1990.

15A NCAC 19A .0104 RELEASE OF COMMUNICABLE DISEASE RECORDS: RESEARCH PURPOSES

(a) A person may request, for bona fide research purposes, the release of records which pertain to a communicable disease or communicable condition and which identify individuals. The request shall be in writing and shall contain the following information:

(1) Name of organization requesting the data;
(2) Names of principal investigators;
(3) Name of project;
(4) Purpose of project;
(5) Description of the proposed use of the data, including protocols for contacting patients, relatives, and service providers;
(6) Descriptions of measures to protect the security of the data;
(7) An assurance that the data will not be used for purposes other than those described in the protocol;
(8) An assurance that the data will be properly disposed of upon completion of the project; and
(9) An assurance that the results of the project will be provided to the custodian of the records.

(b) The request for release of the records shall be granted or denied in writing based upon the following considerations:

(1) Whether the objectives of the project require patient identifying information;
(2) Whether the objective of the project can be reached with the use of the data;
(3) Whether the project has a reasonable chance of answering a legitimate research question;
(4) Whether the project might jeopardize the ability of the Epidemiology Division to obtain reports and information regarding communicable diseases and communicable conditions;
(5) Whether the patient's right to privacy would be adequately protected.

History Note: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-143(9);
Eff. March 1, 1988;
Amended Eff. September 1, 1991.

SECTION .0200 - CONTROL MEASURES FOR COMMUNICABLE DISEASES

15A NCAC 19A .0201 - .0203, .0210 - .0212 have been transferred from the Department of Human Resources and recodified from 10 NCAC 7A .0209 - .0212, effective April 4, 1990.

15A NCAC 19A .0201 CONTROL MEASURES - GENERAL

(a) Except as provided in Rules .0202 - .0209 of this Section, the recommendations and guidelines for testing, diagnosis, treatment, follow-up, and prevention of transmission for each disease and condition specified by the American Public Health Association in its publication, Control of Communicable Diseases Manual shall be the required control measures. Control of Communicable Diseases Manual is hereby incorporated by reference including subsequent amendments and editions. Copies of this publication may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. A copy is available for inspection in the Communicable Disease Control Section, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382.

(b) In interpreting and implementing the specific control measures adopted in Paragraph (a) of this Rule, and in devising control measures for outbreaks designated by the State Health Director and for communicable diseases and conditions for which a specific control measure is not provided by this Rule, the following principles shall be used:

(1) control measures shall be those which can reasonably be expected to decrease the risk of transmission and which are consistent with recent scientific and public health information;

(2) for diseases or conditions transmitted by the airborne route, the control measures shall require physical isolation for the duration of infectivity;

(3) for diseases or conditions transmitted by the fecal-oral route, the control measures shall require exclusions from situations in which transmission can be reasonably expected to occur, such as work as a paid or voluntary food handler or attendance or work in a day care center for the duration of infectivity;

(4) for diseases or conditions transmitted by sexual or the blood-borne route, control measures shall require prohibition of donation of blood, tissue, organs, or semen, needle-sharing, and sexual contact in a manner likely to result in transmission for the duration of infectivity.

(c) Persons with congenital rubella syndrome, tuberculosis, and carriers of Salmonella typhi and hepatitis B who change residence to a different local health department jurisdiction shall notify the local health director in both jurisdictions.

(d) Isolation and quarantine orders for communicable diseases and communicable conditions for which control measures have been established shall require compliance with applicable control measures and shall state penalties for failure to comply. These isolation and quarantine orders may be no more restrictive than the applicable control measures.

(e) An individual enrolled in an epidemiologic or clinical study shall not be required to meet the provisions of 15A NCAC 19A .0201 - .0209 which conflict with the study protocol if:

(1) the protocol is approved for this purpose by the State Health Director because of the scientific and public health value of the study, and

(2) the individual fully participates in and completes the study.

History Note: *Authority G.S. 130A-135; 130A-144;*
Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. February 1, 1990; November 1, 1989; August 1, 1988;
Recodified Paragraphs (d), (e) to Rule .0202, Paragraph (i) to Rule .0203 Eff. June 11, 1991;
Amended Eff. August 1, 1998; October 1, 1992; December 1, 1991.

15A NCAC 19A .0202 CONTROL MEASURES - HIV

The following are the control measures for the Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection:

(1) Infected persons shall:

(a) refrain from sexual intercourse unless condoms are used; exercise caution when using condoms due to possible condom failure;

(b) not share needles or syringes, or any other drug-related equipment, paraphernalia, or works that may be contaminated with blood through previous use;

(c) not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast milk;

(d) have a skin test for tuberculosis;

(e) notify future sexual intercourse partners of the infection; if the time of initial infection is known, notify persons who have been sexual intercourse and needle partners since the date of infection; and, if the date of initial infection is unknown, notify persons who have been sexual intercourse and needle partners for the previous year; and

(f) comply with all control measures for HIV infection and AIDS specified in Paragraph (a) of 15A NCAC 19A .0201, in those instances where such control measures do not conflict with other requirements of this Rule.

(2) The attending physician shall:

(a) give the control measures in Item (1) of this Rule to infected patients, in accordance with 15A NCAC 19A .0210;

(b) If the attending physician knows the identity of the spouse of an HIV-infected patient and has not, with the consent of the infected patient, notified and counseled the spouse appropriately, the physician shall list the spouse on a form provided by the Division of Public Health and shall mail the form to the Division; the Division will undertake to counsel the spouse; the attending physician's responsibility to notify exposed and potentially exposed persons is satisfied by fulfilling the requirements of Sub-Items (2)(a) and (b) of this Rule;

(c) advise infected persons concerning proper clean-up of blood and other body fluids;

(d) advise infected persons concerning the risk of perinatal transmission and transmission by breastfeeding.

(3) The attending physician of a child who is infected with HIV and who may pose a significant risk of transmission in the school or day care setting because of open, oozing wounds or because of behavioral abnormalities such as biting shall notify the local health director. The local health director shall consult with the attending physician and investigate the circumstances.

(a) If the child is in school or scheduled for admission and the local health director determines that there may be a significant risk of transmission, the local health director shall consult with an interdisciplinary committee, which shall include appropriate school personnel, a medical expert, and the child's parent or guardian to assist in the investigation and determination of risk. The local health director shall notify the superintendent or private school director of the need to appoint such an interdisciplinary committee.

(i) If the superintendent or private school director establishes such a committee within three days of notification, the local health director shall consult with this committee.

(ii) If the superintendent or private school director does not establish such a committee within three days of notification, the local health director shall establish such a committee.

(b) If the child is in school or scheduled for admission and the local health director determines, after consultation with the committee, that a significant risk of transmission exists, the local health director shall:

(i) notify the parents;

(ii) notify the committee;

(iii) assist the committee in determining whether an adjustment can be made to the student's school program to eliminate significant risks of transmission;

(iv) determine if an alternative educational setting is necessary to protect the public health;

(v) instruct the superintendent or private school director concerning appropriate protective measures to be implemented in the alternative educational setting developed by appropriate school personnel; and

(vi) consult with the superintendent or private school director to determine which school personnel directly involved with the child need to be notified of the HIV infection in order to prevent transmission and ensure that these persons are instructed regarding the necessity for protecting confidentiality.

(c) If the child is in day care and the local health director determines that there is a significant risk of transmission, the local health director shall notify the parents that the child must be placed in an alternate child care setting that eliminates the significant risk of transmission.

(4) When health care workers or other persons have a needlestick or nonsexual non-intact skin or mucous membrane exposure to blood or body fluids that, if the source were infected with HIV, would pose a significant risk of HIV transmission, the following shall apply:

(a) When the source person is known:

(i) The attending physician or occupational health care provider responsible for the exposed person, if other than the attending physician of the person whose blood or body fluids is the source of the exposure, shall notify the attending physician of the source that an exposure has occurred. The attending physician of the source person shall discuss the exposure with the source and shall test the source for HIV infection unless the source is already known to be infected. The attending physician of the exposed person shall be notified of the infection status of the source.

(ii) The attending physician of the exposed person shall inform the exposed person about the infection status of the source, offer testing for HIV infection as soon as possible after exposure and at reasonable intervals up to one year to determine whether transmission occurred, and, if the source person was HIV infected, give the exposed person the control measures listed in Sub-Items (1)(a) through (c) of this Rule. The attending physician of the exposed person shall instruct the exposed person regarding the necessity for protecting confidentiality.

(b) When the source person is unknown, the attending physician of the exposed person shall inform the exposed person of the risk of transmission and offer testing for HIV infection as soon as possible after exposure and at reasonable intervals up to one year to determine whether transmission occurred.

(c) A health care facility may release the name of the attending physician of a source person upon request of the attending physician of an exposed person.

(5) The attending physician shall notify the local health director when the physician, in good faith, has reasonable cause to suspect a patient infected with HIV is not following or cannot follow control measures and is thereby causing a significant risk of transmission. Any other person may notify the local health director when the person, in good faith, has reasonable cause to suspect a person infected with HIV is not following control measures and is thereby causing a significant risk of transmission.

(6) When the local health director is notified pursuant to Item (5) of this Rule, of a person who is mentally ill or mentally retarded, the local health director shall confer with the attending mental health physician or appropriate mental health authority and the physician, if any, who notified the local health director to develop an appropriate plan to prevent transmission.

(7) The Director of Health Services of the North Carolina Department of Correction and the prison facility administrator shall be notified when any person confined in a state prison is determined to be infected with HIV. If the prison facility administrator, in consultation with the Director of Health Services, determines that a confined HIV infected person is not following or cannot follow prescribed control measures, thereby presenting a significant risk of HIV transmission, the administrator and the Director shall develop and implement jointly

a plan to prevent transmission, including making appropriate recommendations to the unit housing classification committee.

(8) The local health director shall ensure that the health plan for local jails include education of jail staff and prisoners about HIV, how it is transmitted, and how to avoid acquiring or transmitting this infection.

(9) Local health departments shall provide testing for HIV infection with pre- and post-test counseling at no charge to the patient. Third party payors may only be billed for HIV counseling and testing when such services are provided as a part of family planning and maternal and child health services. By August 1, 1991, the State Health Director shall designate a minimum of 16 local health departments to provide anonymous testing. Beginning September 1, 1991, only cases of confirmed HIV infection identified by anonymous tests conducted at local health departments designated as anonymous testing sites pursuant to this Sub-Item shall be reported in accordance with 15A NCAC 19A .0102(a)(3). All other cases of confirmed HIV infection shall be reported in accordance with 15A NCAC 19A .0102(a)(1) and (2). Effective September 1, 1994, anonymous testing shall be discontinued and all cases of confirmed HIV infection shall be reported in accordance with 15A NCAC 19A .0102(a)(1) and (2).

(10) Appropriate counseling for HIV testing shall include risk assessment, risk reduction guidelines, appropriate referrals for medical and psychosocial services, and, when the person tested is found to be infected with HIV, control measures. Pre-test counseling may be done in a group or individually, as long as each individual is provided the opportunity to ask questions in private. Post-test counseling must be individualized.

(11) A local health department or the Department may release information regarding an infected person pursuant to G.S. 130A-143(3) only when the local health department or the Department has provided direct medical care to the infected person and refers the person to or consults with the health care provider to whom the information is released.

(12) Notwithstanding Rule .0201(d) of this Section, a local or state health director may require, as a part of an isolation order issued in accordance with G.S. 130A-145, compliance with a plan to assist the individual to comply with control measures. The plan shall be designed to meet the specific needs of the individual and may include one or more of the following available and appropriate services:

(a) substance abuse counseling and treatment;

(b) mental health counseling and treatment; and

(c) education and counseling sessions about HIV, HIV transmission, and behavior change required to prevent transmission.

(13) The Division of Public Health shall conduct a partner notification program to assist in the notification and counseling of partners of HIV infected persons. All partner identifying information obtained as a part of the partner notification program shall be destroyed within two years.

(14) Every pregnant woman shall be given HIV pre-test counseling, as described in 15A NCAC 19A .0202(10), by her attending physician as early in the pregnancy as possible. At the time this counseling is provided, and after informed consent is obtained, the attending physician shall test the pregnant woman for HIV infection, unless the pregnant woman refuses the HIV test.

History Note: *Authority G.S. 130A-133; 130A-135; 130A-144; 130A-145; 130A-148(h);*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. February 1, 1990; November 1, 1989; June 1, 1989;
Temporary Amendment Eff. January 7, 1991 for a period of 180 days to expire on July 6, 1991;
Amended Eff. May 1, 1991;
Recodified from 15A NCAC 19A .0201 (d) and (e) Eff. June 11, 1991;
Amended Eff. August 1, 1995; October 1, 1994; January 4, 1994; October 1, 1992;
Temporary Amendment Eff. June 1, 2001;

Temporary Amendment Eff. February 18, 2002.

15A NCAC 19A .0203 CONTROL MEASURES - HEPATITIS B

(a) The following are the control measures for hepatitis B infection. The infected persons shall:

(1) refrain from sexual intercourse unless condoms are used except when the partner is known to be infected with or immune to hepatitis B;

(2) not share needles or syringes;

(3) not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast milk;

(4) if the time of initial infection is known, identify to the local health director all sexual intercourse and needle partners since the date of infection; and, if the date of initial infection is unknown, identify persons who have been sexual intercourse or needle partners during the previous six months;

(5) for the duration of the infection, notify future sexual intercourse partners of the infection and refer them to their attending physician or the local health director for control measures; and for the duration of the infection, notify the local health director of all new sexual intercourse partners;

(6) identify to the local health director all current household contacts;

(7) be tested six months after diagnosis to determine if they are chronic carriers, and when necessary to determine appropriate control measures for persons exposed pursuant to Paragraph (b) of this Rule;

(8) comply with all control measures for hepatitis B infection specified in Paragraph (a) of 15A NCAC 19A .0201, in those instances where such control measures do not conflict with other requirements of this Rule.

(b) The following are the control measures for persons reasonably suspected of being exposed:

(1) when a person has had a sexual intercourse exposure to hepatitis B infection, the person shall be tested;

(2) after testing, when a susceptible person has had sexual intercourse exposure to hepatitis B infection, the person shall be given a dose appropriate for body weight of hepatitis B immune globulin and hepatitis B vaccination as soon as possible; hepatitis B immune globulin shall be given no later than two weeks after the last exposure;

(3) when a person is a household contact, sexual intercourse or needle sharing contact of a person who has remained infected with hepatitis B for six months or longer, the partner or household contact, if susceptible and at risk of continued exposure, shall be vaccinated against hepatitis B;

(4) when a health care worker or other person has a needlestick, non-intact skin, or mucous membrane exposure to blood or body fluids that, if the source were infected with the hepatitis B virus, would pose a significant risk of hepatitis B transmission, the following shall apply:

(A) when the source is known, the source person shall be tested for hepatitis B infection, unless already known to be infected;

(B) when the source is infected with hepatitis B and the exposed person is:

(i) vaccinated, the exposed person shall be tested for anti-HBs and, if anti-HBs is unknown or below acceptable level, receive hepatitis B vaccination and hepatitis B immune globulin as soon as possible; hepatitis B immune globulin shall be given no later than seven days after exposure;

(ii) not vaccinated, the exposed person shall be given a dose appropriate for body weight of hepatitis B immune globulin immediately and begin vaccination with hepatitis B vaccine within seven days;

(C) when the source is unknown, the determination of whether hepatitis B immunization is required shall be made in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention guidelines.

(5) infants born to HBsAg-positive mothers shall be given hepatitis B vaccination and hepatitis B immune globulin within 12 hours of birth or as soon as possible after the infant is stabilized. Additional doses of hepatitis B vaccine shall be given in accordance with current

published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines. The infant shall be tested for the presence of HBsAg and anti-HBs within 3-9 months after the last dose of the regular series of vaccine; if required because of failure to develop immunity after the regular series, additional doses shall be given in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention guidelines;

(6) infants born to mothers whose HBsAg status is unknown shall be given hepatitis B vaccine within 12 hours of birth and the mother tested. If the tested mother is found to be HBsAg-positive, the infant shall be given hepatitis B immune globulin as soon as possible and no later than seven days after birth;

(7) When an acutely infected person is a primary caregiver of a susceptible infant less than 12 months of age, the infant shall receive an appropriate dose of hepatitis B immune globulin and hepatitis vaccinations in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines.

(c) The attending physician shall advise all patients known to be at high risk, including injection drug users, men who have sex with men, hemodialysis patients, and patients who receive frequent transfusions of blood products, that they should be vaccinated against hepatitis B if susceptible. The attending physician shall also recommend that hepatitis B chronic carriers receive hepatitis A vaccine (if susceptible).

(d) The following persons shall be tested for and reported in accordance with 15A NCAC 19A .0101 if positive for hepatitis B infection:

(1) pregnant women unless known to be infected; and

(2) donors of blood, plasma, platelets, other blood products, semen, ova, tissues, or organs.

(e) The attending physician of a child who is infected with hepatitis B virus and who may pose a significant risk of transmission in the school or day care setting because of open, oozing wounds or because of behavioral abnormalities such as biting shall notify the local health director. The local health director shall consult with the attending physician and investigate the circumstances.

(f) If the child referred to in Paragraph (e) of this Rule is in school or scheduled for admission and the local health director determines that there may be a significant risk of transmission, the local health director shall consult with an interdisciplinary committee, which shall include school personnel, a medical expert, and the child's parent or guardian to assist in the investigation and determination of risk. The local health director shall notify the superintendent or private school director of the need to appoint such an interdisciplinary committee. If the superintendent or private school director establishes such a committee within three days of notification, the local health director shall consult with this committee. If the superintendent or private school director does not establish such a committee within three days of notification, the local health director shall establish such a committee.

(g) If the child referred to in Paragraph (e) of this Rule is in school or scheduled for admission and the local health director determines, after consultation with the committee, that a significant risk of transmission exists, the local health director shall:

(1) notify the parents;

(2) notify the committee;

(3) assist the committee in determining whether an adjustment can be made to the student's school program to eliminate significant risks of transmission;

(4) determine if an alternative educational setting is necessary to protect the public health;

(5) instruct the superintendent or private school director concerning appropriate protective measures to be implemented in the alternative educational setting developed by school personnel; and

(6) consult with the superintendent or private school director to determine which school personnel directly involved with the child need to be notified of the hepatitis B virus infection in order to prevent transmission and ensure that these persons are instructed regarding the necessity for protecting confidentiality.

(h) If the child referred to in Paragraph (e) of this Rule is in day care and the local health director determines that there is a significant risk of transmission, the local health director shall notify the parents that the child must be placed in an alternate child care setting that eliminates the significant risk of transmission.

History Note: *Authority G.S. 130A-135; 130A-144;*

Eff. February 1, 1990;
Amended Eff. October 1, 1990;
Recodified from 15A NCAC 19A .0201(i) Eff. June 11, 1991;
Amended Eff. October 1, 1994, August 1, 1998;
Temporary Amendment Eff. February 18, 2002.

15A NCAC 19A .0204 CONTROL MEASURES - SEXUALLY TRANSMITTED DISEASES

(a) Local health departments shall provide diagnosis, testing, treatment, follow-up, and preventive services for syphilis, gonorrhea, chlamydia, nongonococcal urethritis, mucopurulent cervicitis, chancroid, lymphogranuloma venereum, and granuloma inguinale. These services shall be provided upon request and at no charge to the patient.

(b) Persons infected with, exposed to, or reasonably suspected of being infected with gonorrhea, chlamydia, non-gonococcal urethritis, and mucopurulent cervicitis shall:

(1) Refrain from sexual intercourse until examined and diagnosed and treatment is completed, and all lesions are healed;

(2) Be tested, treated, and re-evaluated in accordance with the STD Treatment Guidelines published by the U.S. Public Health Service. The recommendations contained in the STD Treatment Guidelines shall be the required control measures for testing, treatment, and follow-up for gonorrhea, chlamydia, nongonococcal urethritis, and mucopurulent cervicitis, and are incorporated by reference including subsequent amendments and editions. A copy of this publication is on file for public viewing with the HIV/STD Control Branch located at 225 N. McDowell Street, Cooper Building, Raleigh, N.C. 27611-7687 or a copy may be obtained free of charge by writing the HIV/STD Control Branch, P.O. Box 27687, Raleigh, N.C. 27611-7687, and requesting a copy. However, urethral Gram stains may be used for diagnosis of males rather than gonorrhea cultures unless treatment has failed;

(3) Notify all sexual partners from 30 days before the onset of symptoms to completion of therapy that they must be evaluated by a physician or local health department.

(c) Persons infected with, exposed to, or reasonably suspected of being infected with syphilis, lymphogranuloma venereum, granuloma inguinale, and chancroid shall:

(1) Refrain from sexual intercourse until examined and diagnosed and treatment is completed, and all lesions are healed;

(2) Be tested, treated, and re-evaluated in accordance with the STD Treatment Guidelines published by the U.S. Public Health Service. The recommendations contained in the STD Treatment Guidelines shall be the required control measures for testing, treatment, and follow-up for syphilis, lymphogranuloma venereum, granuloma inguinale, and chancroid, except that chancroid cultures shall not be required;

(3) Give names to a disease intervention specialist employed by the local health department or by the HIV/STD Control Branch for contact tracing of all sexual partners and others as listed in this Rule:

(A) for syphilis:

(i) congenital - all immediate family members;

(ii) primary - all partners from three months before the onset of symptoms to completion of therapy and healing of lesions;

(iii) secondary - all partners from six months before the onset of symptoms to completion of therapy and healing of lesions; and

(iv) latent - all partners from 12 months before the onset of symptoms to completion of therapy and healing of lesions and, in addition, for women with late latent, spouses and children;

(B) for lymphogranuloma venereum:

(i) if there is a primary lesion and no buboes, all partners from 30 days before the onset of symptoms to completion of therapy and healing of lesions; and

(ii) if there are buboes all partners from six months before the onset of symptoms to completion of therapy and healing of lesions;

(C) for granuloma inguinale - all partners from three months before the onset of symptoms to completion of therapy and healing of lesions; and

(D) for chancroid - all partners from ten days before the onset of symptoms to completion of therapy and healing of lesions.

(d) All persons evaluated or reasonably suspected of being infected with any sexually transmitted disease shall be tested for syphilis, encouraged to be tested confidentially for HIV, and counseled about how to reduce the risk of acquiring sexually transmitted disease, including the use of condoms.

(e) All pregnant women shall be tested for syphilis and gonorrhea early in pregnancy and in the third trimester. Pregnant women at high risk for exposure to syphilis and gonorrhea shall also be tested for syphilis and gonorrhea at the time of delivery.

(f) All newborn infants shall be treated prophylactically against gonococcal ophthalmia neonatorum in accordance with the STD Treatment Guidelines published by the U. S. Public Health Service. The recommendations contained in the STD Treatment Guidelines shall be the required prophylactic treatment against gonococcal ophthalmia neonatorum.

History Note: *Authority G. S. 130A-135; 130A-144;*
Eff. December 1, 1991;
Amended Eff. July 1, 1993.

15A NCAC 19A .0205 CONTROL MEASURES - TUBERCULOSIS

(a) The local health director shall promptly investigate all cases of tuberculosis disease and their contacts in accordance with the provisions of Control of Communicable Diseases Manual. Control of Communicable Diseases Manual is hereby incorporated by reference including subsequent amendments and editions. Copies of this publication may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. A copy is available for inspection in the Communicable Disease Control Section, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382.

(b) The following persons shall be skin tested for tuberculosis and given appropriate clinical, microbiologic and x-ray examination in accordance with the "Diagnostic Standards and Classification of Tuberculosis," published by the American Thoracic Society. The recommendations contained in this reference shall be the required control measures for evaluation, testing, and diagnosis for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions:

(1) Household and other close contacts of active cases of pulmonary and laryngeal tuberculosis. If the initial skin test is negative (0-4mm), and the case is confirmed by culture, a repeat skin test shall be performed three months after the exposure has ended;

(2) Persons reasonably suspected of having tuberculosis disease;

(3) Inmates in the custody of, and staff with direct inmate contact in, the Department of Corrections upon incarceration or employment, and annually thereafter;

(4) Patients and staff in long term care facilities upon admission or employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months;

(5) Staff in adult day care centers providing care for persons with HIV infection or AIDS upon employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months;

(6) Persons with HIV infection or AIDS.

A copy of "Diagnostic Standards and Classification of Tuberculosis" is available, at no charge, by contacting the Department of Environment, Health, and Natural Resources, Tuberculosis Control Branch, Post Office Box 29601, Raleigh, North Carolina 27626-0601.

(c) Treatment and follow-up for tuberculosis infection or disease shall be in accordance with "Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children," published by the American Thoracic Society. The recommendations contained in this reference shall be the required control measures for testing, treatment, and follow-up for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions. Copies of this publication are available, at no charge, by contacting the Department of Environment and Natural Resources, Tuberculosis Control Branch, Post Office Box 29601, Raleigh, North Carolina 27626-0601.

(d) The attending physician or designee shall instruct all patients treated for tuberculosis regarding the potential side effects of the medications prescribed and to promptly notify the physician or designee if side effects occur.
(e) Persons with active tuberculosis disease shall complete a standard drug regimen from "Treatment of Tuberculosis and Tuberculosis Infections in Adults and Children."
(f) Persons with suspected or known active pulmonary or laryngeal tuberculosis are considered infectious and shall be managed using airborne precautions, including respiratory isolation, or quarantined in their home, with no new persons exposed, if:

(1) They have sputum smears which are positive for acid fast bacilli; and
(2) They have not received tuberculosis drug therapy or have just started therapy; and
(3) They have no evidence of clinical response or have poor clinical response to therapy.

(g) Persons with suspected or known active pulmonary or laryngeal tuberculosis are considered noninfectious and use of airborne precautions, including respiratory isolation, or quarantine in their home may be discontinued when:

(1) They have three consecutive daily sputum smears which are negative; or
(2) They have been compliant on tuberculosis medications to which the organism is judged to be susceptible, there is evidence of clinical improvement on the therapy, and the environment to which they are being released is such that transmission of tuberculosis organisms is unlikely.

History Note: *Authority G.S. 130A-135; 130A-144;*
Eff. March 1, 1992;
Amended Eff. August 1, 1998; October 1, 1994.

15A NCAC 19A .0206 INFECTION CONTROL - HEALTH CARE SETTINGS

(a) The following definitions shall apply throughout this Rule:

(1) "Health care organization" means hospital; clinic; physician, dentist, podiatrist, optometrist, or chiropractic office; home health agency; nursing home; local health department; community health center; mental health agency; hospice; ambulatory surgical center; urgent care center; emergency room; or any other health care provider that provides clinical care.
(2) "Invasive procedure" means entry into tissues, cavities, or organs or repair of traumatic injuries. The term includes but is not limited to the use of needles to puncture skin, vaginal and cesarean deliveries, surgery, and dental procedures during which bleeding occurs or the potential for bleeding exists.

(b) Health care workers, emergency responders, and funeral service personnel shall follow blood and body fluid precautions with all patients.
(c) Health care workers who have exudative lesions or weeping dermatitis shall refrain from handling patient care equipment and devices used in performing invasive procedures and from all direct patient care that involves the potential for contact of the patient, equipment, or devices with the lesion or dermatitis until the condition resolves.
(d) All equipment used to puncture skin, mucous membranes, or other tissues in medical, dental, or other settings must be disposed of in accordance with 15A NCAC 13B after use or sterilized prior to reuse.
(e) In order to prevent transmission of HIV and hepatitis B from health care workers to patients, each health care organization that performs invasive procedures shall implement a written infection control policy by July 1, 1993. The health care organization shall ensure that health care workers in its employ or who have staff privileges are trained in the principles of infection control and the practices required by the policy; require and monitor compliance with the policy; and update the policy as needed to prevent transmission of HIV and hepatitis B from health care workers to patients. The health care organization shall designate a staff member to direct these activities. By September 1, 1994 the designated staff member in each health care organization shall have completed a course in infection control approved by the Department. The course shall address:

(1) Epidemiologic principles of infectious disease;
(2) Principles and practice of asepsis;
(3) Sterilization, disinfection, and sanitation;
(4) Universal blood and body fluid precautions;
(5) Engineering controls to reduce the risk of sharp injuries;
(6) Disposal of sharps; and

(7) Techniques which reduce the risk of sharp injuries to health care workers.

(f) The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV and hepatitis B from infected health care workers to patients:

(1) Sterilization and disinfection, including a schedule for maintenance and microbiologic monitoring of equipment; the policy shall require documentation of maintenance and monitoring;

(2) Sanitation of rooms and equipment, including cleaning procedures, agents, and schedules;

(3) Accessibility of infection control devices and supplies;

(4) Procedures to be followed in implementing 15A NCAC 19A .0202(4) and .0203(b)(3) when a health care provider or a patient has an exposure to blood or other body fluids of another person in a manner that poses a significant risk of transmission of HIV or hepatitis B.

History Note: *Authority G.S. 130A-144; 130A-145;*
Eff. October 1, 1992;
Amended Eff. July 1, 1994; January 4, 1994.

15A NCAC 19A .0207 HIV AND HEPATITIS B INFECTED HEALTH CARE WORKERS

(a) The following definitions shall apply throughout this Rule:

(1) "Surgical or obstetrical procedures" means vaginal deliveries or surgical entry into tissues, cavities, or organs. The term does not include phlebotomy; administration of intramuscular, intradermal, or subcutaneous injections; needle biopsies; needle aspirations; lumbar punctures; angiographic procedures; endoscopic and bronchoscopic procedures; or placing or maintaining peripheral or central intravascular lines.

(2) "Dental procedure" means any dental procedure involving manipulation, cutting, or removal of oral or perioral tissues, including tooth structure during which bleeding occurs or the potential for bleeding exists. The term does not include the brushing of teeth.

(b) All health care workers who perform surgical or obstetrical procedures or dental procedures and who know themselves to be infected with HIV or hepatitis B shall notify the State Health Director. Health care workers who assist in these procedures in a manner that may result in exposure of patients to their blood and who know themselves to be infected with HIV or hepatitis B shall also notify the State Health Director. The notification shall be made in writing to the Chief, Communicable Disease Control Section, P.O. Box 27687, Raleigh, N.C. 27611-7687.

(c) The State Health Director shall investigate the practice of any infected health care worker and the risk of transmission to patients. The investigation may include review of pertinent medical and work records and consultation with health care professionals who may have information necessary to evaluate the clinical condition or practice of the infected health care worker. The attending physician of the infected health care worker shall be consulted. The State Health Director shall protect the confidentiality of the infected health care worker and may disclose the worker's infection status only when essential to the conduct of the investigation or periodic reviews pursuant to Paragraph (h) of this Rule. When the health care worker's infection status is disclosed, the State Health Director shall give instructions regarding the requirement for protecting confidentiality.

(d) If the State Health Director determines that there may be a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel to evaluate the risk of transmission to patients, and review the practice, skills, and clinical condition of the infected health care worker, as well as the nature of the surgical or obstetrical procedures or dental procedures performed and operative and infection control techniques used. Each expert panel shall include an infectious disease specialist, and infection control expert, a person who practices the same occupational specialty as the infected health care worker and, if the health care worker is a licensed professional, a representative of the appropriate licensure board. The panel may include other experts. The State Health Director shall consider for appointment recommendations from health care organizations and local societies of health care professionals.

(e) The expert panel shall review information collected by the State Health Director and may request that the State Health Director obtain additional information as needed. The State Health Director shall not reveal to the panel the identity of the infected health care worker. The infected health care worker and the health care

worker's attending physician shall be given an opportunity to present information to the panel. The panel shall make recommendations to the State Health Director that address the following:

(1) Restrictions that are necessary to prevent transmission from the infected health care worker to patients;

(2) Identification of patients that have been exposed to a significant risk of transmission of HIV or hepatitis B; and

(3) Periodic review of the clinical condition and practice of the infected health care worker.

(f) If, prior to receipt of the recommendations of the expert panel, the State Health Director determines that immediate practice restrictions are necessary to prevent an imminent threat to the public health, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require cessation or modification of some or all surgical or obstetrical procedures or dental procedures to the extent necessary to prevent an imminent threat to the public health. This isolation order shall remain in effect until an isolation order is issued pursuant to Paragraph (g) of this Rule or until the State Health Director determines the imminent threat to the public health no longer exists.

(g) After consideration of the recommendations of the expert panel, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require any health care worker who is allowed to continue performing surgical or obstetrical procedures or dental procedures to, within a time period specified by the State Health Director, successfully complete a course in infection control procedures approved by the Department of Environment, Health, and Natural Resources, Communicable Disease Control Section, in accordance with 15A NCAC 19A .0206(e). The isolation order shall require practice restrictions, such as cessation or modification of some or all surgical or obstetrical procedures or dental procedures, to the extent necessary to prevent a significant risk of transmission of HIV or hepatitis B to patients. The isolation order shall prohibit the performance of procedures that cannot be modified to avoid a significant risk of transmission. If the State Health Director determines that there has been a significant risk of transmission of HIV or hepatitis B to a patient, the State Health Director shall notify the patient or assist the health care worker to notify the patient.

(h) The State Health Director shall request the assistance of one or more health care professionals to obtain information needed to periodically review the clinical condition and practice of the infected health care worker who performs or assists in surgical or obstetrical procedures or dental procedures.

(i) An infected health care worker who has been evaluated by the State Health Director shall notify the State Health Director prior to a change in practice involving surgical or obstetrical procedures or dental procedures. The infected health care worker shall not make the proposed change without approval from the State Health Director. If the State Health Director makes a determination in accordance with Paragraph (c) of this Rule that there is a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel in accordance with Paragraph (d) of this Rule. Otherwise, the State Health Director shall notify the health care worker that he or she may make the proposed change in practice.

(j) If practice restrictions are imposed on a licensed health care worker, a copy of the isolation order shall be provided to the appropriate licensure board. The State Health Director shall report violations of the isolation order to the appropriate licensure board. The licensure board shall report to the State Health Director any information about the infected health care worker that may be relevant to the risk of transmission of HIV or hepatitis B to patients.

History Note: *Authority G.S. 130A-144; 130A-145;*
Eff. October 1, 1992.

15A NCAC 19A .0208 CONTROL MEASURES -- SMALLPOX; VACCINIA DISEASE

(a) Guidelines and recommended actions for prevention of the spread of smallpox and for prevention of the spread of vaccinia published by the Center for Disease Control and Prevention (CDC) shall supercede those contained in the control of Communicable Disease Manual and are incorporated by reference, including subsequent amendments and editions. Copies of CDC guidelines contained in the Morbidity and Mortality weekly reports may be purchased from the Superintendent of Documents, US Government Printing Office, Washington DC 20402 for a total cost of three dollars and fifty cents ($3.50) each.

(b) The attending physician of a person vaccinated against smallpox shall report to the local health department the existence of any of the following:

(1) autoinnoculation;

(2) generalized vaccinia;
(3) eczema vaccinatum;
(4) progressive vaccinia; and
(5) post vaccination encephalitis.

The attending physician shall make the report to the local health department within 24 hours. The local health department shall notify the division of Public Health within 24 hours.

(c) The physician responsible for vaccinating a person against smallpox and the physician diagnosing a person with vaccinia disease shall instruct the patient to follow CDC guidelines for the prevention of the spread of vaccinia adopted by reference in Paragraph (a) of this Rule. The patient shall follow these guidelines.

(d) The State Health Director or a local health director may use isolation authority pursuant to G.S. 130A-145 when necessary to prevent the spread of smallpox or vaccinia virus.

History Note: *Authority G. S. 130A-144;*
Temporary Adoption Eff. February 13, 2003.

15A NCAC 19A .0209 LABORATORY TESTING

All laboratories are required to do the following:

(1) When Neisseria meningitidis is isolated from a normally sterile site, test the organism for specific serogroup or send the isolate to the State Public Health Laboratory for serogrouping;
(2) When a stool culture is requested on a specimen from a person with bloody diarrhea, culture the stool for shiga-toxin producing Escherichia coli or send the specimen to the State Public Health Laboratory; and
(3) When Haemophilus influenzae is isolated, test the organism for specific serogroup or send the isolate to the State Public Health Laboratory for serogrouping.

History Note: *Authority G.S. 130A-139;*
Eff. October 1, 1994;
Temporary Amendment Eff. February 18, 2002.

15A NCAC 19A .0210 DUTIES OF ATTENDING PHYSICIANS

Immediately upon making a diagnosis of or reasonably suspecting a communicable disease or communicable condition for which control measures are provided in Rule .0201, .0202 or .0203 of this Section, the attending physician shall instruct the patient and any other person specified in those control measures to carry out those control measures and shall give sufficiently detailed instructions for proper compliance, or the physician shall request the local health director to give such instruction. When making the initial telephone report for diseases and conditions required to be reported within 24 hours, the physician shall inform the local health director of the control measures given.

History Note: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-144;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0202 Eff. June 11, 1991.

15A NCAC 19A .0211 DUTIES OF OTHER PERSONS

(a) The local health director may reveal the identity and diagnosis of a person with a reportable communicable disease or communicable condition or other communicable disease or communicable condition which represents a significant threat to the public health to those persons specified in Paragraph (b) when disclosure is necessary to prevent transmission in the facility or establishment for which they are responsible. The local health director shall ensure that all persons so notified are instructed regarding the necessity for protecting confidentiality.

(b) The following persons shall require that any person about whom they are notified pursuant to Paragraph (a) comply with control measures given by the local health director to prevent transmission in the facility or establishment:

(1) the principal of any private or public school;
(2) employers;
(3) superintendents or directors of all public or private institutions, hospitals, or jails; and
(4) operators of a child day care center, child day care home, or other child care providers.

(c) The provisions of Paragraphs (a) and (b) shall not apply with regard to gonorrhea, syphilis, chancroid, granuloma inguinale, lymphogranuloma venereum, chlamydia, non-gonococcal urethritis, AIDS, and HIV infection. However, persons may be notified with regard to these diseases and conditions in accordance with 15A NCAC 19A .0201, .0202 or .0203 of this Section.

History Note: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-143; 130A-144;
Eff. March 1, 1988;
Amended Eff. June 1, 1989;
Recodified from 15A NCAC 19A .0203 Eff. June 11, 1991.

15A NCAC 19A .0212 HANDLING AND TRANSPORTATION OF BODIES

(a) It shall be the duty of the physician attending any person who dies and is known to have smallpox, plague, HIV infection, hepatitis B infection, rabies, or Jakob-Creutzfeldt to provide written notification to all individuals handling the body of the proper precautions to prevent infection. This written notification shall be provided to funeral service personnel at the time the body is removed from any hospital, nursing home, or other health care facility. When the patient dies in a location other than a health care facility, the attending physician shall notify the funeral service personnel verbally of the precautions required as soon as the physician becomes aware of the death. These precautions are noted in Paragraphs (b) and (c).

(b) The body of a person who died from smallpox or plague shall not be embalmed. The body shall be enclosed in a strong, tightly sealed outer case which will prevent leakage or escape of odors as soon as possible after death and before the body is removed from the hospital room, home, building, or other premises where the death occurred. This case shall not be reopened except with the consent of the local health director.

(c) Persons handling bodies of persons who died and were known to have HIV infection, hepatitis B infection, Jakob-Creutzfeldt, or rabies shall be provided written notification to observe blood and body fluid precautions.

History Note: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-144; 130A-146;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0204 Eff. June 11, 1991.

SECTION .0300 - SPECIAL CONTROL MEASURES

15A NCAC 19A .0301 - .0302 have been transferred from the Department of Human Resources and recodified from 10 NCAC 7A .0301 - .0302, effective April 4, 1990.

15A NCAC 19A .0301 DEFINITIONS

The following definitions shall apply in the interpretation of 15A NCAC 19A .0302:

(1) "Turtle" means any reptile of the order Testudines.
(2) "Institution" means a school, college, university, research laboratory, or other facility having a bona fide research or teaching interest in turtles.

History Note: *Authority G.S. 130A-144;*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. May 1, 1992.

15A NCAC 19A .0302 SALE OF TURTLES RESTRICTED

(a) Purpose of this Regulation. This Regulation is adopted to prevent the spread of salmonellosis from pet turtles to humans.

(b) Sale of Turtles Prohibited. No turtle shall be sold, offered for sale, or bartered by any retail or wholesale establishment in North Carolina.

(c) Sale of Turtles for Scientific, Educational, or Food Purposes Exempted. Subsection (b) of this Regulation does not apply to the sale of turtles to institutions for scientific or educational purposes nor to the sale of turtles for food purposes.

(d) Sale of Turtles Outside North Carolina Exempted. Notwithstanding the provisions of Subsection (b) of this Regulation, wholesale establishments in North Carolina dealing in the sale of turtles shall not be prohibited from selling turtles to other wholesale or retail establishments outside the State of North Carolina.

(e) Determination of Compliance. Authorized agents of the Department of Environment, Health, and Natural Resources and local health departments shall have authority to enter any retail or wholesale establishment at all times to determine compliance with this Regulation.

History Note: *Authority G.S. 130A-144;*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. February 3, 1992.

15A NCAC 19A .0303 RECORDING THE SALES OF BIRDS

(a) A business engaged in the retail sale of birds shall maintain a record of each sale for at least six months after the sale. The record shall include the name and address of the purchaser of each bird. The record shall be made available to the Department upon the request of the Department.

(b) This Rule shall not apply to the sale of birds for hunting, scientific, educational, agricultural or food purposes.

History Note: *Authority G.S. 130A-144;*
Eff. June 1, 1990.

SECTION .0400 – IMMUNIZATION

15A NCAC 19A .0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

(a) Every individual in North Carolina required to be immunized pursuant to G.S. 130A-152 through 130A-157 shall be immunized against the following diseases by receiving the specified minimum doses of vaccines by the specified ages:

(1) Diphtheria, tetanus, and whooping cough vaccine - five doses: three doses by age seven months and two booster doses, one by age 19 months and the second on or after the fourth birthday and before enrolling in school (K-1) for the first time. However:

(A) An individual who has attained his or her seventh birthday without having been immunized against whooping cough shall not be required to be immunized with a vaccine preparation containing whooping cough antigen;

(B) Individuals who receive the first booster dose of diphtheria, tetanus, and whooping cough vaccine on or after the fourth birthday shall not be required to have a second booster dose;

(C) Individuals attending school, college or university or who began their tetanus/diphtheria toxoid series on or after the age of seven years shall be required to have three doses of tetanus/diphtheria toxoid of which one must have been within the last 10 years.

(D) The requirements for booster doses of diphtheria, tetanus, and whooping cough vaccine shall not apply to individuals who enrolled for the first time in the first grade before July 1, 1987.

(2) Poliomyelitis vaccine--four doses: two doses of trivalent type by age five months; a third dose trivalent type before age 19 months, and a booster dose of trivalent type on or after the fourth birthday and before enrolling in school (K-1) for the first time. However:

(A) An individual attending school who has attained his or her 18th birthday shall not be required to receive polio vaccine;

(B) Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday shall not be required to receive a fourth dose;

(C) The requirements for booster doses of poliomyelitis vaccine shall not apply to individuals who enrolled for the first time in the first grade before July 1, 1987.

(3) Measles (rubeola) vaccine--two doses of live, attenuated vaccine administered at least 30 days apart: one dose on or after age 12 months and before age 16 months and a second dose before enrolling in school (K-1) for the first time. However:

(A) An individual who has been documented by serological testing to have a protective antibody titer against measles shall not be required to receive measles vaccine;

(B) An individual who has been diagnosed prior to January 1, 1994, by a physician licensed to practice medicine as having measles (rubeola) disease shall not be required to receive measles vaccine;

(C) An individual born prior to 1957 shall not be required to receive measles vaccine;

(D) The requirement for a second dose of measles vaccine shall not apply to individuals who enroll in school (K-1) or in college or university for the first time before July 1, 1994.

(4) Rubella vaccine--one dose of live, attenuated vaccine on or after age 12 months and before age 16 months. However:

(A) An individual who has been documented by serologic testing to have a protective antibody titer against rubella shall not be required to receive rubella vaccine;

(B) An individual who has attained his or her fiftieth birthday shall not be required to receive rubella vaccine except in outbreak situations;

(C) An individual who entered a college or university after his or her thirtieth birthday and before February 1, 1989 shall not required to meet the requirement for rubella except in outbreak situations.

(5) Mumps vaccine--one dose of live, attenuated vaccine administered on or after age 12 months and before age 16 months. However:

(A) An individual born prior to 1957 shall not be required to receive mumps vaccine;

(B) The requirements for mumps vaccine shall not apply to individuals who enrolled for the first time in the first grade before July 1, 1987 or in college or university before July 1, 1994.

(C) An individual who has been documented by serological testing to have a protective antibody titer against mumps shall not be required to receive mumps vaccine.

(6) *Haemophilus influenzae, b*, conjugate vaccine--three doses of HbOC or PRP-T or two doses of PRP-OMP before age seven months and a booster dose of any type on or after age 12 months and by age 16 months.

However:

(A) Individuals born before October 1, 1988 shall not be required to be vaccinated against *Haemophilus influenzae, b;*

(B) Individuals who receive the first dose of *Haemophilus influenzae, b*, vaccine on or after 12 months of age and before 15 months of age shall be required to have only two doses of HbOC, PRP-T or PRP-OMP;

(C) Individuals who receive the first dose of *Haemophilus influenzae, b*, vaccine on or after 15 months of age shall be required to have only one dose of any of the *Haemophilus influenzae* conjugate vaccines, including PRP-D.

(D) No individual who has passed their fifth birthday shall be required to be vaccinated against *Haemophilus influenzae, b.*

(7) Hepatitis B vaccine--three doses: one dose by age three months, a second dose before age five months and a third dose by age 19 months.

(A) The third dose of hepatitis B vaccine shall not be administered prior to 6 months of age;

(B) Individuals born before July 1, 1994 shall not be required to be vaccinated against hepatitis B.

(8) Varicella vaccine--1 dose administered on or after age 12 months and before age 19 months. However:

(A) An individual with a laboratory test indicating immunity or with a history of varicella disease, documented by a health care provider, parent, guardian or person in loco parentis shall not be required to receive varicella vaccine. Serologic proof of immunity or documentation of previous illness must be presented whenever a certificate of immunization is required by North Carolina General Statute. The documentation shall include the name of the individual with a history of varicella disease and the approximate date or age of infection. Previous illness shall be documented by:

(i) a written statement from a health care provider documented on or attached to the lifetime immunization card or certificate of immunization; or

(ii) a written statement from the individual's parent, guardian or person in loco parentis attached to the lifetime immunization card or certificate of immunization.

(B) An individual born prior to April 1, 2001 shall not be required to receive varicella vaccine.

(9) The healthcare provider shall administer immunizations in accordance with this Rule. However, if a healthcare provider administers vaccine up to and including the fourth day prior to the required minimum age, the individual dose will not be required to be repeated. Doses administered more than four days prior to the requirements are considered invalid doses and shall be repeated.

(b) The State Health Director may suspend temporarily any portion of the requirements of these immunization rules due to emergency conditions, such as the unavailability of vaccine. The Department shall give notice in writing to all local health departments and other providers currently receiving vaccine from the Department when the suspension takes effect and when the suspension is lifted. When any vaccine series is disrupted by such a suspension, the next dose shall be required to be administered within 90 days of the lifting of the suspension and the series resumed in accordance with intervals determined by the most recent recommendations of the Advisory Committee on Immunization Practices.

History Note: *Authority G.S. 130A-152(c); 130A-155.1;*
Eff. February 1, 1976;
Amended Eff. July 1, 1977;
Readopted Eff. December 5, 1977;
Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Amended Eff. October 1, 1995; October 1, 1994; January 1, 1994; January 4, 1993;
Filed as a Temporary Amendment Eff. May 21, 1999;
Temporary Amendment Eff. February 23, 2000; August 20, 1999;
Amended Eff. August 1, 2000;

Temporary Amendment Eff. May 17, 2002; April 1, 2002; February 18, 2002; August 1, 2001.

15A NCAC 19A .0402 APPROVED VACCINE PREPARATIONS

All vaccine preparations licensed for interstate use by the Bureau of Biologic Standards of the U.S. Food and Drug Administration are approved for use in fulfilling the requirements of 10 NCAC 7A .0401.

History Note: *Authority G.S. 130A-152(c);*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977.

15A NCAC 19A .0403 NON-RELIGIOUS PERSONAL BELIEF NO EXEMPTION

Except as provided in G.S. 130A-156 and G.S. 130A-157, and 15A NCAC 19A .0404 and .0405, no child shall be exempt from the requirements of 15A NCAC 19A .0401; there is no exception to these requirements for the case of a personal belief or philosophy of a parent or guardian not founded upon a religious belief.

History Note: *Authority G.S. 130A-152(c);*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. October 1, 1984; July 1, 1979.

15A NCAC 19A .0404 MEDICAL EXEMPTIONS FROM IMMUNIZATION

(a) Certification of a medical exemption by a physician pursuant to G.S. 130A-156 shall be in writing and shall state the basis of the exemption, the specific vaccine or vaccines the individual should not receive, and the length of time the exemption will apply for the individual.

(b) Medical contraindications for which medical exemptions may be certified by a physician for immunizations are included in the most recent General Recommendations of the Advisory Committee on Immunization Practices, Public Health Services, U.S. Department of Health and Human Services, published in the Centers for Disease Control and Prevention publication, the Morbidity and Mortality Weekly Report, which is adopted by reference including subsequent amendments and additions. A copy is available for inspection in the Immunization Section at 1330 St. Mary's Street, Raleigh, North Carolina. Internet access is available by searching www.cdc.gov/nip.

History Note: *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-152(c); 130A-156;
Eff. July 1, 1979;
Amended Eff. August 1, 2000; January 4, 1993; February 1, 1990; March 1, 1988.

15A NCAC 19A .0405 EXEMPTION FOR CLINICAL STUDIES

An individual enrolled in a clinical trial of the efficacy of a new vaccine preparation or dosage schedule shall be exempted from those requirements of 15A NCAC 19A .0401 and .0402 which conflict with the trial protocol. This exemption shall only apply to individuals who:

(1) participate in a clinical trial whose protocol is approved by the State Health Director, and
(2) fully participate in and complete the clinical trial.

History Note: *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on*
July 29, 1988;
Authority G.S. 130A-152(c);
Eff. October 1, 1983;

Amended Eff. March 1, 1988.

15A NCAC 19A .0406 ACCESS TO IMMUNIZATION INFORMATION

(a) Physicians, local health departments and the Department shall, upon request and without consent release the immunization information specified in Paragraph (b) of this Rule to the following organizations:

(1) schools K-12, whether public, private or religious;
(2) licensed and registered childcare facilities as defined in G.S. 110-86(3) and G.S. 110-101;
(3) Head Start;
(4) colleges and universities, whether public, private or religious;
(5) Health Maintenance Organizations; and
(6) Other state and local health departments outside of North Carolina.

(b) The following is the immunization information to be released to the organizations specified in Paragraph (a) of this Rule:

(1) name and address;
(2) name of the parent, guardian, or person standing *in loco parentis;*
(3) date of birth;
(4) gender;
(5) race and ethnicity;
(6) vaccine type, date and dose number administered;
(7) the name and address of the physician or local health department that administered each dose; and
(8) the existence of a medical or religious exemption determined by the Immunization Section to meet the requirements of G.S. 130A-156 and 15A NCAC 19A .0404 or G.S. 130A-157. If such a determination has not been made by the Immunization Section, the person shall have access to the certification of medical and religious exemptions required by G.S. 130A-156 or G.S. 130A-157 and 15A NCAC 19A .0404.

History Note: *Authority G.S. 130A-153;*
Filed as a Temporary Adoption Eff. August 9, 1993, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. April 1, 2001; August 1, 2000; October 1, 1995.

SECTION .0500 - PURCHASE AND DISTRIBUTION OF VACCINE

15A NCAC 19A .0500 was transferred from the Department of Human Resources, 15A NCAC 19A .0501 recodified from 10 NCAC 7A .0501, 15A NCAC 19A .0502 - .0503 recodified from 10 NCAC 7A .0503 - .0504, effective April 4, 1990.

15A NCAC 19A .0501 PURCHASE OF VACCINE

The Department of Environment, Health, and Natural Resources may enter into contracts for the purchase of vaccines. Any purchase of such vaccines shall be in accordance with Article 3 of G.S. 143 and 1 NCAC 5A.

History Note: *Filed as a Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;*
Authority S.L. 1986, c. 1008, s. 2;
Eff. February 1, 1987;
Amended Eff. September 1, 1991.

15A NCAC 19A .0502 VACCINE FOR PROVIDERS OTHER THAN LOCAL HEALTH DEPARTMENTS

(a) The Department of Environment, Health, and Natural Resources shall provide vaccines required by law free of charge to the following providers for administration to individuals who need vaccines to meet the requirement of G.S. 130A-152, 130-155.1 and 15A NCAC 19A .0401:

(1) Community, migrant, and rural health centers;
(2) Colleges and universities for students; and
(3) Physicians and other health care providers.

(b) Upon request of the Department, required vaccines may be distributed by local health departments operating as agents of the State to providers listed in Subparagraphs (a)(1), (2) and (3) of this Rule.

(c) Providers authorized in Paragraph (a) of this Rule shall be eligible to receive free vaccines from the Department only if they sign an agreement with the Department. This agreement will be prepared by the Immunization Section and will require the provider to:

(1) Charge no more for a single dose of vaccine than the rate established by the Health Care Financing Administration (HCFA); Charge no more than double the HCFA rate as a reasonable fee for the administration of two or more vaccines given at a single visit. The rate established by HCFA is published in the Federal Register (59FR50235), and is incorporated herein by reference along with any subsequent amendments and editions. The HCFA rate may be inspected at the Immunization Section of the Department of Environment, Health, and Natural Resources. Copies may also be obtained from the Immunization Section at no charge;
(2) Provide all vaccines needed during a visit unless a specific contraindication exists to one or more of the vaccine;
(3) Charge no office fee in addition to an administration fee for an immunization-only visit;
(4) Agree not to charge an administration fee to an individual who states that they are unable to pay;
(5) Impose no condition as a prerequisite to receiving vaccine;
(6) The providers shall submit a monthly doses administered report by the tenth of each month electronically through the North Carolina Immunization Registry or on a form provided by the Immunization Section.
(7) Report adverse vaccine reactions through the Vaccine Adverse Event Reporting System (VAERS);
(8) Provide the latest edition of the applicable Important Information Statement (IIS), or Vaccine Information Statement (VIS) to the parent, guardian, or person standing in loco parentis for each dose of vaccine administered; document this action within the patient's permanent medical record; retain the documentation for a period of 10 years following the end of the calendar year in which the vaccine dose was administered, or for 10 years following the recipient's age of majority, whichever is longer; upon request, furnish copies of the documentation to the local health department or the Department. Keep a record of the vaccine manufacturer, lot number, and date of administration for each dose of vaccine administered;
(9) Allow periodic inspection of their vaccine supplies and records by the Immunization Section; and
(10) Comply with the rules of this Section.

(d) A provider who fails to submit timely and accurate reports as required each month shall have vaccine shipments withheld until that month’s report is received by the Immunization Section.

History Note: *Filed as a Temporary Amendment Eff. October 1, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Filed as a Temporary Amendment Eff. August 26, 1992, for a period 180 days or until the permanent rule becomes effective, whichever is sooner;
Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Filed as a Temporary Rule Eff. February 1, 1987 for a period of 120 days to expire on May 31, 1987;

Filed as Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;
Authority G.S. 130A-152; 130A-155.1; 130A-433; S.L. 1986, c. 1008, s. 2; S.L. 1987, c. 215, s. 7;
Eff. March 1, 1987;
Amended Eff. October 1, 1995; January 1, 1995; January 4, 1994; January 4, 1993;
Temporary Amendment Eff. December 1, 1998;
Amended Eff. August 1, 2000.

15A NCAC 19A .0503 DISTRIBUTION OF VACCINE TO COLLEGES AND UNIVERSITIES

History Note: *Filed as a Temporary Repeal Eff. August 25, 1992, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 130A-155.1; 130A-433;
Eff. February 1, 1990;
Repealed Eff. January 4, 1993.

SECTION .0600 - SPECIAL PROGRAM/PROJECT FUNDING

15A NCAC 19A .0601 - .0605 have been transferred from the Department of Human Resources and recodified from 10 NCAC 7A .0601 - .0605, effective April 4, 1990.

15A NCAC 19A .0601 GENERAL

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988;
Repealed Eff. September 1, 1990.

15A NCAC 19A .0602 PROVIDER ELIGIBILITY

The following organizations are eligible to apply for special project funds from the Division of Epidemiology:

(1) local health departments; and
(2) Non-profit or governmental groups such as public health, educational, and voluntary organizations.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

15A NCAC 19A .0603 APPLICATION FOR FUNDS

(a) Grants for special projects shall be awarded through a request for proposal (RFP) process that includes notification of all local health departments of the eligibility criteria, requirements for funding, and duration of the project period. This information shall also be available to other groups or organizations who may wish to apply. Requests for proposals may be obtained from the Division of Epidemiology, Post Office Box 27687, Raleigh, NC 27611-7687.

(b) The grant proposal shall include the following:

(1) a project plan which includes an assessment of the need for the special project, measurable project objectives, and strategies for meeting the project objectives;
(2) a proposed budget; and
(3) an evaluation plan.

(c) In making the determination of which applications to approve for funding, each proposal will be judged on its own merits in competition with all the other proposals submitted to the Section. Proposals shall be judged according to the following criteria:

(1) the proposal demonstrates that a substantial need exists;
(2) the proposed project makes a significant contribution in meeting the established need; and
(3) the proposed project can be successfully completed within a reasonable period of time.

(d) The Division of Epidemiology shall review all grant proposals submitted on or before the deadline for submission of proposals. The Division of Epidemiology shall approve or deny a grant proposal within 60 days after the deadline for receipt of the grant proposal.

(e) A contract shall be signed with each applicant that is approved for funding. The number and type of services to be provided under the contract shall be negotiated with each contractor, approved by the Division of Epidemiology, and included as an addendum to the contract. Contracts may be renewed upon expiration of the contract period when the contractor's proposal meets the criteria in (c)(1) of this Rule, the contractor has demonstrated adequate performance, and funds are available.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988;
Amended Eff. September 1, 1990.

15A NCAC 19A .0604 REPORTS

(a) The contractor shall submit periodic performance reports as specified in the contract.

(b) The contractor shall submit a final report at the close of the contract period. The report shall include an evaluation addressing progress in meeting the objectives outlined in the application.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

15A NCAC 19A .0605 USE OF SPECIAL PROJECT FUNDS

(a) Special Project Funds provided pursuant to these Rules shall be expended solely for the purposes for which the funds were made available in accordance with the approved application, negotiated project objectives and budget, the rules in this Section, the terms and conditions of the award, and the applicable state costs principles.

(b) A contractor that consistently fails to meet acceptable levels of performance, as determined through site visits, review of performance reports, and other appropriate and generally accepted performance standards, and has been offered consultation and technical assistance, may have special project funds reduced or discontinued. Recommendations to reduce or discontinue funding shall be reviewed and approved by the State Health Director.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

SECTION .0700 - FEDERAL AIDS DRUG REIMBURSEMENT PROGRAM

15A NCAC 19A .0701 MEDICAL ELIGIBILITY

History Note: *Authority G.S. 130A-5(3);*
Eff. October 1, 1990;
Transferred and Recodified as 15A NCAC 16A .1001 Eff. August 10, 1992.

SECTION .0800 - COMMUNICABLE DISEASE GRANTS AND CONTRACTS

15A NCAC 19A .0801 COMMUNICABLE DISEASE FINANCIAL GRANTS AND CONTRACTS

(a) The Communicable Disease Control Section may enter into financial arrangements with local health departments, community hospitals, nursing homes, or other convalescent facilities, and with physicians for the purpose of providing specific health care services for communicable diseases and the implementation of the control measures prescribed in this Rule.

(b) The HIV/STD Control Branch may authorize a local health department to obtain required diagnostic and treatment services for persons with syphilis, gonorrhea, chancroid, lymphogranuloma venereum, and granuloma inguinale from physicians:

(1) The amount to be charged for these services shall be negotiated between the local health department and the physician and approved by the HIV/STD Control Branch at the lowest agreeable rate, not to exceed approved Medicaid reimbursement rates. Drugs used in treatment may be provided to such physicians by the local health department.

(2) The physician shall bill the local health department for services provided. The local health department shall submit requests for payment to the HIV/STD Control Branch on forms provided by the Division of Epidemiology.

(c) The Tuberculosis Control Branch may:

(1) Contract with hospitals to provide inpatient diagnostic and hospitalization services for eligible tuberculosis patients if:

(A) Private rooms with negative air pressure with respect to the hallways and other rooms are available;

(B) A qualified physician is willing to accept inpatient referrals from surrounding counties;

(C) There is a laboratory that performs mycobacterial studies at the hospital;

(D) There is a radiological department at the hospital, including a radiologist;

(E) There is an infection control program at the hospital to monitor the staff and patients to minimize the occurrence of nosocomial tuberculosis infection;

(F) There is a program at the hospital to ensure that the risk for employees developing or transmitting tuberculosis is low; and

(G) Funds are available.

(2) Contract with licensed nursing homes or other convalescent facilities to provide inpatient treatment and convalescent care to eligible tuberculosis patients if:

(A) Private rooms with negative air pressure with respect to the hallways and other rooms are available;

(B) A qualified physician is willing to accept inpatient referrals;

(C) There is an infection control program to monitor the staff and patients to minimize the occurrence of nosocomial tuberculosis infection;

(D) There is a program to ensure that the risk for employees developing or transmitting tuberculosis is low;

(E) Necessary laboratory tests, radiological and transportation services are available at the facility, through contracts, or by some other arrangement; and

(F) Funds are available.

History Note: *Authority G. S. 130A-5; 130A-135; 130A-144;*
Eff. December 1, 1991.

15A NCAC 19A .0802 ELIGIBILITY FOR TUBERCULOSIS HOSPITALIZATION SERVICES

(a) A patient shall be medically eligible for payment for up to seven days inpatient hospitalization for diagnosis of tuberculosis at a hospital designated by the Tuberculosis Control Branch pursuant to Rule .0801 of this

Section and the patient is suspected of having Mycobacterium tuberculosis disease based upon the finding of one or more of the following:

(1) Evidence of acid-fast bacilli found by direct microscopy or by culture techniques;
(2) Histopathologic evidence of tuberculosis in an active form;
(3) Positive tuberculin skin test reaction using intermediate strength purified protein derivative (PPD), five tuberculin units and suggestive symptoms;
(4) X-ray or clinical evidence suggestive of the presence of tuberculosis in an active form; or
(5) Epidemiologic information supportive of a diagnosis of tuberculosis in an active form.

(b) If a patient is diagnosed as having Mycobacterium tuberculosis by a physician licensed to practice medicine in this State, then the patient shall be medically eligible for up to 21 days of hospitalization per year beginning the first day of financial eligibility for the treatment of the disease and for the cost of ambulance services from the contracting hospital to a program-designated medical facility.

(c) If the head of the Tuberculosis Control Branch determines that additional treatment is medically necessary because of the tuberculosis condition, the head of the Branch may extend the period of medical eligibility beyond the periods specified in Paragraph (a) and (b) of this Rule.

(d) The medical care payments described in this Rule are available only for services provided at a hospital which has contracted with the Tuberculosis Program for these services.

(e) Financial eligibility and payment procedures shall be determined in accordance with requirements for medical care payments found in 15A NCAC 24A.

History Note: *Authority G. S. 130A-5; 130A-135; 130A-144;*
Eff. December 1, 1991.

15A NCAC 19A .0803 ELIGIBILITY FOR TUBERCULOSIS NURSING HOME SERVICES

(a) A patient shall be medically eligible for reimbursement for up to 60 days per year for treatment and convalescent services at a nursing home designated by the Tuberculosis Control Branch pursuant to Rule .0801 of this Section provided the following criteria are met:

(1) The applicant has active pulmonary or disseminated tuberculosis associated with incapacitation or significant debilitation which requires a SNF or ICF level of care. To aid in making this determination, the referring physician shall provide a treatment plan and project a length of stay for the patient at the nursing home.
(2) The applicant has positive bacteriology for tuberculosis. The positive bacteriology (AFB) must have been obtained within the preceding 14 days.
(3) The applicant does not need an acute level of hospital care for any condition.
(4) The applicant is 16 years of age or over.
(5) The applicant is referred by a licensed physician who has first-hand knowledge of the applicant's mental and physical condition. The referring physician shall furnish a summary of the applicant's physical and mental condition and known infirmities, and specific details of treatment and medication the applicant is taking with orders for dosage, frequency and duration. This summary shall include all known allergies and previous reactions to anti-tuberculosis and all other medications. In addition, dietary needs, pertinent x-rays, and copies of laboratory reports shall be forwarded with the patient or in advance.
(6) The head of the Tuberculosis Control Branch may make exceptions to the criteria contained in Subparagraphs (1) through (5) of this Paragraph if the patient would be best treated for tuberculosis at a licensed nursing home.

(b) If the head of the Tuberculosis Control Branch determines that additional treatment or convalescent care at a licensed nursing home is medically necessary because of tuberculosis, the head of the Branch may extend medical eligibility for more than 60 days per year.

(c) Financial eligibility and payment procedures shall be determined in accordance with 15A NCAC 24A.

History Note: *Authority G. S. 130A-5; 130A-135; 130A-144;*
Eff. December 1, 1991.

SECTION .0900 - BIOLOGICAL AGENT REGISTRY

15A NCAC 19A .0901 GENERAL

The biological agent registry established by G.S. 130A-149 is administered by the N.C. Department of Health and Human Services, Division of Public Health, Epidemiology Section, 225 N. McDowell Street, Raleigh, N.C. 27603.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0902 BIOLOGICAL AGENTS TO BE REPORTED

The biological agents that shall be reported to the registry shall be those agents listed as select agents in 42 C.F.R. Part 72, Appendix A which is adopted herein by reference including subsequent amendments and editions. Copies of this federal provision may be inspected at and copies obtained from the N.C. Department of Health and Human Services, Division of Public Health, Epidemiology Section, 225 N. McDowell Street, Raleigh, N.C. 27603, at a cost of ten cents ($.10) per page at the time of adoption of this Rule.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0903 WHEN TO REPORT

A person possessing and maintaining a listed biological agent on the effective date of these Rules shall make a report within 45 days of the effective date of these Rules. A person who does not possess and maintain any listed biological agents on the effective date of these Rules shall make a report within seven days of receipt of such agents. A person shall make an amended report within seven days of any change in the information contained in the report. A person shall make a report within 24 hours of any suspected release, loss or theft of any listed biological agent.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0904 WHAT TO REPORT

The report shall be made on a form created by the Department and shall identify the listed biological agents possessed and maintained at the facility; shall specify the use of the agents for vaccine production, research purposes, quality control or other use; shall indicate the form of the agents; shall identify the physical location of the laboratories and the storage areas; and shall identify the person in charge of the agents.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0905 EXEMPTION FROM REPORTING

A person who detects a listed biological agent in a clinical or environmental sample for the purpose of diagnosing disease, epidemiological surveillance, exposure assessment, reference, verification or proficiency testing, and who discards the agent within 14 calendar days of receiving notice of the completion of confirmation testing, or discards the agent within 14 calendar days of using the agent for reference, verification or proficiency testing, is not required to make a report.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0906 SECURITY

All persons possessing and maintaining a listed biological agent must demonstrate compliance with all safeguards contained in 42 C.F.R. Part 72 and the rules promulgated thereunder, and must employ those federal safeguards over the agents they possess and maintain, regardless of whether the mere possession of the agent is itself required to be registered under federal law. The safeguards contained in 42 C.F.R. Part 72 and the rules promulgated thereunder are adopted herein by reference including subsequent amendments and additions. Copies of this federal provision may be inspected at and copies obtained from the N.C. Department of Health and Human Services, Division of Public Health, Epidemiology Section, 225 N. McDowell Street, Raleigh, N.C. 27603, at a cost of ten cents ($.10) per page at the time of adoption of this Rule.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.

15A NCAC 19A .0907 RELEASE OF INFORMATION

The Department shall release information contained in the Biological Agents Registry only by order of the State Health Director upon a finding that the release is necessary for the conduct of a communicable disease investigation or for the investigation of a release, theft or loss of a biological agent.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002.